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510(K) SUMMARY
FOR THE
SIREMOBIL ISO-C 3D IMAGING OPTION

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

October 17, 2000

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Ms. Amy Shaw Hosler
Phone: (732) 321-4830
Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name:	Siremobil Iso-C 3D imaging option
Classification Name:	Accessory to Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	90IZL

3. Substantial Equivalence:

The Siremobil Iso-C 3D software option is designed for three-dimensional evaluation of data acquired with an isocentric mobile C-arm device. The package is substantially equivalent to the following devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Siremobil Iso-C	K973598	11/10/97
Siemens 3D Angio	K984634	3/12/99

4. Device Description:

The 3D-Imaging Option is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with an isocentric, mobile C-arm device into a three-dimensional image format.

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5. **Intended Use of the Device:**
The Siremobil Iso-C 3D is intended to be used whenever the surgeon benefits from intraoperatively generated 3D information of high contrast objects (bones and joints). The Siremobil Iso-C 3D focuses on complex bone or joint fractures of the upper and lower extremities (including knee, foot, elbow, hand), and the cervical spine.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
Both the Siemens Siremobil Iso-C 3D Imaging Option and Siemens 3D-Angio software option allow reconstruction of a three-dimensional model from a series of two dimensional images acquired with a C-arm imaging device.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2000

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
Sales and Service
186 Wood Avenue South
Iselin, NJ 08830

Re: K003266
Siremobil Iso-C 3D Imaging Option
Dated: October 17, 2000
Received: October 18, 2000
Regulatory class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Ms. Rutherford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

510(k) Number (if known): K003266
Device Name: Siremobil Iso-C 3D Imaging Option

Indications For Use:

The Siremobil Iso-C 3D Imaging Option is based on Siemens isocentric mobile C-arm, marketed as Siremobil Iso-C. The 3D imaging option of the Siremobil Iso-C 3D contains hardware for the motorized movement of the orbital axis, a 3D workstation and a software package for volume reconstruction from two-dimensional images, 3D post-processing and visualization.

The Siremobil Iso-C 3D is intended to be used whenever the surgeon benefits from intraoperatively generated 3D information of high contrast objects and anatomical structures (e.g. bones and joints). The Siremobil Iso-C 3D is designed as a 3D imaging device for conditions such as complex bone or joint fractures of the upper and lower extremities (including knee, foot, elbow, hand), and the cervical spine.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Bogenn

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003266

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)